



DEPARTMENT OF HEALTH AND HUMAN SERVICE

5401901

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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May 16, 2003

WARNING LETTER NO. 2003-NOL-16

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Ronald J. Noel, Co-Owner
Atchafalaya Crawfish Processors, Inc.
1702 B – Grand Anse Highway
Breux Bridge, Louisiana 70517

Dear Mr. Noel:

We inspected your firm, located at 1509 B Henderson Highway, Henderson, Louisiana, on March 31 – April 3, 2003, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 C.F.R. § 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 C.F.R. § 110. In accordance with 21 C.F.R. § 123.6(g), “failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part” renders the processor’s fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your crawfish tail meat is adulterated in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA’s home page at www.fda.gov.

Please note that our investigators collected a sample of cooked, peeled crawfish tail meat at

Atchafalaya Crawfish Processors, Inc. The sample subsequently was analyzed for the presence of microorganisms. *Escherichia coli* (*E. coli*) was recovered from the sample collected on April 1, 2003. You already may have received a letter from our Southeast Regional Laboratory in Atlanta, Georgia notifying you of this finding. The presence of *E. coli* causes your crabmeat to be in violation of Section 402(a)(3) of the Act.

E. coli is part of the normal intestinal flora of humans or other primates. The presence of *E. coli* in your crabmeat is an indication of fecal contamination. Some strains of *E. coli* cause food borne bacterial illness, such as gastroenteritis, that can be a serious illness for some people;

especially the elderly, newborns, and those with weakened immune systems. Food processors and handlers should take all precautions necessary to reduce the risk of contamination and to keep food safe from *E. coli*. We strongly recommend that you determine the cause of this problem and take corrective action as soon as possible.

The deviations observed during the inspection of your facility were as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 C.F.R. §§ 123.6(a) and (c)(2). A critical control point is defined in 21 C.F.R. § 123.3(b) as a “point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.” However, your firm’s HACCP plan for vacuum-packaged, cooked crawfish tail meat does not list the critical control point of label receipt to control the food safety hazard of *Clostridium botulinum* (*C. botulinum*) toxin formation.

We particularly are concerned with your failure to identify and to implement controls in your HACCP plan to control *C. botulinum* toxin formation in your vacuum-packaged crawfish tail meat, which is stored frozen and labeled to keep refrigerated. Unless this product is maintained in a frozen condition until immediately before use by the consumer, the only control to prevent toxin production by *C. botulinum* for this product is storage below 38°F, which requires constant monitoring of refrigeration during processor storage and distribution, as well as at the wholesale and retail level. Moreover, if the product is frozen until immediately before use by the consumer, it should be labeled with adequate storage instructions (e.g. “Important, keep frozen until used, thaw under refrigeration immediately before use”).

- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 C.F.R. § 123.6(b). However, your firm did not follow the monitoring procedures that are listed in your HACCP plan for cooked crawfish:
 - a) Colanders of cooked crawfish tail meat were observed on the peeling tables longer than the [] specified in your HACCP plan. For example, on March 31, 2003, the investigators observed crawfish tail meat on a peeling table from 1½ to 2 hours after the cook operation and with internal temperatures ranging from 78°F to 102°F; and,
 - b) Packages of vacuum-packaged crawfish tail meat were stored under refrigerated conditions for several days after production. Your HACCP plan calls []
[]
- You must implement the record keeping system listed in your HACCP plan to comply with 21 C.F.R. §§ 123.6(b) and 6(c)(7). However, your firm did not record monitoring observations at the peeling critical control point to control pathogen growth and toxin formation as listed in your HACCP plan for cooked crawfish tail meat. In addition, your firm’s HACCP plan does not specify the monitoring procedure.

In addition, the investigator documented numerous insanitary conditions that cause your product to be adulterated within the meaning of Section 402(a)(4) of the Act.

The deviations were as follows:

- Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of the food with microorganisms or foreign substances. For example:
 - a) A cooking employee was observed touching uncooked crawfish and then cooked crawfish without washing or sanitizing his gloves;
 - b) An employee touched her hair and then proceeded to peel crawfish without washing and sanitizing her hands; and,
 - c) An employee was observed blowing her nose with a paper towel, getting more crawfish from the supply bin, then peeling the crawfish without washing or sanitizing her hands.
- You are not sanitizing utensils, equipment, and employee hands in a manner that protects food and food contact surfaces from contamination. For example, the concentration of iodine at 12 ppm is not adequate to sanitize food contact surfaces.
- You have not taken reasonable measures and precautions to ensure that persons working in direct contact with food wear the appropriate hair nets, headbands, caps, beard covers or other effective hair restraints. For example, two employees peeling crawfish were observed with hair protruding from the hair net.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

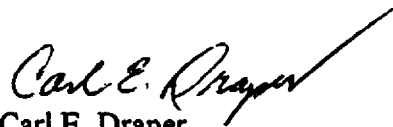
During our inspection, you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within 15 working days from your receipt of this letter, outlining specific actions that you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your corrective action to products determined to be contaminated with *E. coli* in distribution channels, your revised HACCP plan, vacuum packaging label, copies of temperature monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

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Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl E. Draper", with a long, sweeping horizontal stroke extending to the right.

Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483

cc: Judy Noel, Co-Owner and Secretary
Atchafalaya Processors, Inc.
1702 B – Grand Anse Highway
Breux Bridge, Louisiana 70517